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Title: Enhancing patient safety: New WHO guidance on pharmacovigilance in tuberculosis care

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Body: Adverse drug reactions (ADRs) can lead to a patient interrupting tuberculosis (TB) treatment before completion, and contribute to avoidable morbidity, treatment failure, loss in quality of life, or death. While many national TB control programmes have a long tradition of monitoring patient care, the surveillance of drug-related problems, or pharmacovigilance, has not been systematic. The increasing worldwide use of more extensive regimens for drug-resistant TB, the concomitant use of antiretroviral therapy in patients with HIV-associated TB, and the imminent release on the market of new classes of medicines to treat TB make the case for pharmacovigilance even stronger. WHO produced guidance this year on pharmacovigilance for TB through the financial support of the European Commission Seventh Framework Programme. The manual discusses how pharmacovigilance can be effectively implemented in a programme through key stakeholders, and provides a step-by-step approach on how to identify signals, assess relationships between an event and a drug, determine causality, and communicate findings. It presents three methodologies of pharmacovigilance which can be applied for the detection, assessment, understanding and prevention of adverse events or any other drug-related problem under field situations. The first two - spontaneous and targeted spontaneous reporting - can be built into national programmes of routine pharmacovigilance and/or tuberculosis control. The third type, cohort event monitoring (CEM), is an active form of surveillance, similar in design and management to an epidemiological cohort study. CEM would be particularly well suited to the post-marketing surveillance of new drugs.